REMARKS

The specification has been amended to more clearly indicate the priority chain for this application and reflects what is provided on the Official Filing Receipt mailed by the US PTO on October 30, 2003.

Claims 25, 29-31 and 33-35 are hereby newly canceled. Claims 36-53 are newly added. As a result of this amendment, claims 36-53 are currently pending.

The present application is a divisional application of U.S. Patent Application No. 09/719,771, which issued as U.S. Patent No. 6,635,756 ("the '756 patent"). Each of the currently pending method and plant claims in the present application have been amended so as to correspond with the language utilized in the issued starch claims of the '756 patent. Support for each of the amendments can be found throughout the as-filed specification and the originally filed claims. No new matter has been entered via these amendments.

Claim Rejections – 35 USC § 112

Claims 25, 29-31 and 33-35 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In summary, the Office Action asserts that undue experimentation would be required by one skilled in the art to accomplish the claimed methods and obtain the claimed plants.

In an effort to advance prosecution, Applicants have hereby canceled all of the previously pending claims and added new claims that track closely the language utilized in the issued starch claims of the '756 patent, which issued from the parent application of the present application. Applicants' comments which follow are directed to the rejection in as much as it could arguably be seen as applying to the newly presented claims.

The Examiner relies upon Patron *et al.* (Plant Physiology 2002, 130:190-198) and Edwards *et al.* (The Plant Cell 2002, 14:1767-1785) to support his contention that "the effect of starch synthase genes on starch content and structure is unpredictable". The research reported in Patron *et al.* deals with low-amylose barley mutants with a 413-bp deletion in GBSSI which alters the spatial and/or temporal expression of the enzyme in the endosperm (page 196, beginning of first full paragraph). This article does not support the Examiner's position that the effect of starch synthase on "starch content and structure is unpredictable" (emphasis added).

The article does not address starch structure, other than observing that it is low in amylose due to the *waxy* mutation. Each of the currently pending claims is directed to a plant or method which produces starch with particular characteristics/structure as a result of introducing nucleic acids, wherein the nucleic acids encode two different starch synthase genes. Edwards *et al.* deals with the differences in the amylose produced in plants/cells with two isoforms of GBSSI in peas, which is clearly different that the focus of the present invention and the pending claims. The Office Action states that it would require undue experimentation "to isolate and evaluate the effects of all the starch synthase genes on starch content and structure in a heterologous transgenic plant" (page 4, lines 2-4). Applicants' presently claimed invention is not directed to introducing isoforms of starch synthase genes. In contrast, the currently pending claims are directed to altering starch characteristics produced by a plant by introducing into the plant at least two heterologous nucleic acid sequences, wherein the nucleic acid sequences encode different starch synthase enzymes.

The Examiner also relies upon Salehuzzaman *et al.* (1999, Plant, Cell and Environment 22:1311-1318) in support of his contention that the "effect of a gene transformed into a different plant background is unpredictable when it is related to specific biosynthetic pathways peculiar to particular plant species" (page 4, first full paragraph). Salehuzzaman *et al.* discusses transforming a potato plant with a single cassava GBSSI gene. The present invention is directed to altering starch characteristics by introducing two heterologous nucleic acid sequences, wherein each encodes a different starch synthase gene. The fact that Salehuzzaman *et al.* "found that amylose content was only partially restored" is not relevant to Applicants' invention for obtaining starch with particular characteristics/structure.

The Office Action also states that undue experimentation would have been required by one skilled in the art to perform the invention of the previously-pending claims (page 5, first full paragraph). Applicants assert that anyone skilled in the art of plant genetics and plant breeding can accomplish the claimed invention by merely transforming a plant with at least two heterologous nucleic acid sequences, wherein each nucleic acid sequence encodes a different starch synthase enzyme, and then testing the starch of such transformed plants to determine whether or not that starch meets the claimed limitations. Such transformation and testing procedures are routine in the art of plant genetics/breeding. Although such experimentation can

be somewhat time consuming and tedious, this does not mean that it is undue. Applicants have provided a roadmap for those skilled in the art to produce transformed plants with starch having the characteristics set forth in the claims, wherein no undue experimentation is necessary to obtain such plants/starch.

For all of the above reasons, the Examiner is respectfully requested to withdraw this rejection.

Claims 25, 29-31 and 33-35 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In summary, the Office Action asserts that the claims allegedly contain subject matter which is not described in the specification. More specifically, the Office Action asserts "the specification only provides guidance for the transformation of a potato plant with a construct containing partial cDNAs of potato starch synthase II and potato starch synthase III" and "does not provide guidance for the transformation of any other plant species with any other starch synthases or any other embodiments of potato starch synthase II or potato starch synthase III" (page 6, first full paragraph). Applicants' comments which follow are directed to the rejection in as much as it could arguably be seen as applying to the newly presented claims.

Contrary to the Examiner's assertions, Applicants provided a list of representative starch synthase genes to use in the claimed invention (see, *e.g.*, page 6, second full paragraph; paragraph bridging pages 10-11; page 11, second full paragraph) as well as representative methods for producing the claimed transformed plants (see, *e.g.*, page 13-14; Example 1, A/B, pages 16-18; Example 2, A/B, pages 22-24) and methods of analyzing the starch of the transformed plants (see, *e.g.*, column 10, second full paragraph; Example 1, C, page 18; Example 2, C, pages 24-25; Example 3, pages 28-30). Applicants assert that anyone skilled in the art of plant genetics/breeding can practice the claimed invention based on these disclosures in the as-filed specification.

At the time the present application was filed in mid-1998, one skilled in the art of plant genetics/breeding who was in possession of Applicants' disclosure clearly would have been able to obtain or isolate a nucleic acid sequence for a variety of heterologous synthase enzymes, transform a variety of different plants with such sequences and test the starch obtained from such

transformed plants to see if that starch has the characteristics set forth in the presently pending claims. Applicants have described a representative number of species of the claimed genus so that one skilled in the art could "visualize or recognize the identity of the members of the genus" (*University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398 (Fed. Cir. 1997).

For all of the above reasons the Examiner is respectfully requested to withdraw the rejection.

Claim Rejections – 35 USC § 102

Claims 25, 29-31 and 33-35 stand rejected under 35 U.S.C. 102(a) as allegedly being anticipated by Lolyd *et al.* (1999 Biochem. J. 338:515-521). Applicants note that the Examiner has cited this reference on Form PTO-892 even though Applicants had already cited this reference to the US PTO at page 5 of the Form PTO-1449, a copy of which was attached to the Office Action and initialed by the Examiner as having been considered.

This application is a divisional of application Serial No. 09/719,771 filed March 5, 2001, now U.S. Patent No. 6,635,756, which is a 371 of PCT/GB99/01902, filed June 15, 1999, which claims priority to EP 98304716 filed on June 15, 1998.

In accordance with M.P.E.P. § 706.02(b), Applicants have hereby amended the specification to more clearly state that priority is claimed to foreign priority document EP 98304716. This foreign priority claim was acknowledged in the parent application (see, *e.g.*, Office Action Summary in the '771 application mailed on February 25, 2003) and the US PTO has stated that "copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau." A courtesy copy of the foreign priority document is attached hereto and, as further required by M.P.E.P. § 706.02(b), a review of that document verifies that it clearly satisfies the enablement and description requirement of 35 U.S.C. 112, first paragraph.

The cited Lolyd *et al.* reference was published sometime in 1999. The priority date of EP 98304716 is June 15, 1998. Therefore, the filing date of the priority document for the present application predates the cited reference.

The Examiner is respectfully requested to withdraw this rejection in view of: (a) the amendment to the specification clearly stating that priority is claimed to EP 98304716, which was filed in 1998; (b) that EP 98304716 satisfies the enablement and written description requirements of 35 U.S.C. 112, first paragraph, for at least the presently claimed invention; and (c) EP 98304716 was filed before the publication date of the cited Lolyd *et al.* reference.

Claims 25, 30 and 32-35 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Block *et al.* (WO 9745545). Applicants note that the Examiner has cited this reference on Form PTO-892 even though Applicants had already cited this reference to the US PTO at page 3 of the Form PTO-1449, a copy of which was attached to the Office Action and initialed by the Examiner as having been considered. Applicants further note that the copy of WO 9745545 provided by the US PTO is missing pages 13-15, wherein these specific pages were cited by the Examiner. Applicants obtained and reviewed a complete copy of the cited reference before replying herein. Applicants will address the Block *et al.* reference in as much as it could arguably be seen as applying to the newly presented claims.

This application is a divisional of application Serial No. 09/719,771 filed March 5, 2001, now U.S. Patent No. 6,635,756, which is a 371 of PCT/GB99/01902, filed June 15, 1999, which claims priority to EP 98304716 filed on June 15, 1998. Therefore, even if the Examiner maintains that the Block et al. publication is somehow pertinent to the presently pending claims the reference fails to be a 102(b) reference since it published on December 4, 1997, which is well within one year of the priority filing date the present application.

Block *et al.* fail to adequately teach or suggest stably transforming a plant with at least two heterologous nucleic acid sequences each encoding a different starch synthase enzyme so as to produce the starch as set forth in the methods and plants of the newly presented claim set. Even more specifically, Block et al. fail to teach methods or transformed plants which produce starch with the particular characteristics as claimed in the newly presented claim set, wherein such starch is the claimed subject matter of U.S. Patent No. 6,635,756.

The Examiner is respectfully requested to withdraw this rejection for each of the above reasons.

Claim Rejections – 35 USC § 103

Claims 25, 29-31 and 33-35 stand rejected under 35 U.S.C. 103(a) as allegedly being obvious over Block *et al.* (WO9745545). The examiner alleges that the teachings of Block *et al.* render the claimed invention obvious because one skilled in the art could modify the method taught by Block *et al.* by transforming more than one nucleic acid encoding enzymes of starch synthase activity into a plant to achieve a plant producing starch wherein the viscosity onset temperature is reduced by at least 12 degrees centigrade.

Applicants traverse this rejection and wish to point out that the presently claimed invention defines specific properties of the starch that is produced by the method or the plant, which is the claimed subject matter of U.S. Patent No. 6,635,756. Applicants submit that Block *et al.* fail to adequately teach or suggest stably transforming a plant with at least two heterologous nucleic acid sequences each encoding a different starch synthase enzyme so as to produce the starch as defined in the methods and plants of the presently pending claim set. Block *et al.* provide no suggestion of a method or a transformed plant that produces the starch as characterized in the pending claims. The Examiner is respectfully requested to withdraw this rejection for the above reasons.

CONCLUSION

It is respectfully submitted that the above-identified application is now in a condition for allowance and favourable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact the applicant's undersigned attorney at the telephone number listed below.

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Respectfully submitted,
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